REMARKS/ARGUMENTS

Claims 75-94 are active. Minor corrections have been made to the specification. Support for the new claims is found in the original claims and specification as follows: claims 75-79 and 93-94 (claim 24, page 3, 2nd and 3rd full paragraphs; page 4, line 3), claim 80 (bottom of page 4), claim 81 (page 17, first full paragraph, page 24, Example 2), claim 82 (claims 6-7, page 8, page 19, line 14 *ff.*), claim 83 (page 11, line 11), claim 84 (claims 9, 19, and 20, bottom of page 17; page 7, line 19), claims 85-86 (claims 19-22, page 18, 2nd paragraph), claim 87 (page 11, first paragraph), claims 88-89 (claims 1 and 25, pages 8 and 10, bottoms), claim 90 claim 42, page 3, 2nd and 3rd full paragraphs) and claims 90-92 (claims 12-13, page 14, line 8 *ff.*) (claim 39). In view of the above, the Applicants do not believe that any new matter has been introduced. The Applicants respectfully request reconsideration of the issues of record in view of these amendments and the remarks which follow.

Restriction/Lack of Unity/Election

The Applicants previously elected with traverse **Group I**, claims 24-59 and 72-74, directed to a method for stimulating/treating hair growth involving administration of a polynucleotide of SEQ ID NO: 1, and the species **saponins** (described in the Requirement as a second hair growth stimulating agent). SEQ ID NO: 1 and SEQ ID NO: 3 encode human or murine IL-15 polypeptides, respectively (specification, page 3, last four lines).

Claims 75-90 are generic and encompass methods which may employ the elected species saponin. The requirement has been made FINAL. The Applicants understand that additional species will be rejoined and examined upon an indication of allowability for a generic claim reading on the elected species. The Applicants respectfully request that the claims of the nonelected group(s) or any other withdrawn subject matter which depend from

or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04.

Objection—Sequence Compliance

The previously-filed Sequence Listing and CRF were objected to as not complying with the sequence rules. Page 3 of the Preliminary Amendment filed August 13, 2007 contains a statement regarding the identity of the electronic and printed copies of the substitute Sequence Listing. However, the Applicants are happy to reiterate this statement below referring to the pertinent sequence rules. Accordingly, this issue is moot in view of the statement below.

Sequence Listing Statement

As required by 37 C.F.R. 1.821(f), the sequence information recorded in the computer-readable form (CRF) of the substitute Sequence Listing filed August 13, 2007 is identical to that in the paper copy of the substitute Sequence Listing; or if this substitute Sequence Listing is electronically-filed, then the sequences in the electronically filed Sequence Listing are identical to the sequences disclosed in this application. Pursuant to 37 C.F.R. 1.821(g) the Applicants state that no new matter has been introduced.

Oath/Declaration and Information Disclosure Statements (IDS)

The Applicants thank Examiner Long for indicating that these documents are in compliance or have been formally considered.

Priority—Sequence Listing

This is a national-stage filing under §371 of PCT/EP04/13907. This PCT is not a priority document, rather the present U.S. application is the national-stage of this PCT. As apparent from the WO 2005/063279 A1 (attached, the published PCT application), the subject matter in the sequence listing is part of the original disclosure and does not constitute new matter. The substitute Sequence Listing filed August 13, 2007 merely revises the original sequence listing to comply with U.S. requirements. Accordingly, the substitute sequence listing does not introduce new matter and has the same effective filing date as the rest of the disclosure. The Applicants respectfully request that the Examiner confirm that the substitute sequence listing contains no new matter.

Rejection—35 U.S.C. §112, first paragraph

Claims 24-26, 33-44, 51-59 and 72-74 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description. This rejection is moot in view of the cancellation of the prior claims. It would not apply to the present claims for the following reasons.

A. The broader claims, directed to a polynucleotide that is at least 95% identical to SEQ ID NO: 1 meet the description requirements by analogy to Example 11A of the PTO *Written Description Training Materials* (Revision 1, March 25, 2008). The recitation of "at least 95% identity" represents a partial structure, that is at least 95% of the nucleotides will match those in SEQ ID NO: 1 and up to 5% of them may vary from those in SEQ ID NO: 1. With the aid of a computer one could have identified all polynucleotide sequences that are at least 95% identical to SEQ ID NO: 1. Further, as apparent from the title of Example 11A, a structure-function relationship is not required to meet the description requirement. Thus, one

of ordinary skill in the art would have concluded that the applicant was in possession of the claimed genus at the time the application was filed.

B. For even stronger reasons, this rejection would not apply to claims, such as claim 77-79, which are directed to specific polynucleotide sequences or to polynucleotides encoding specific polypeptides.

Accordingly, this rejection is now moot and would not apply to the new claims.

Rejection—35 U.S.C. §112, first paragraph

Claims 24-26, 33-44, 51-59 and 72-74 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement. This rejection is moot in view of the cancellation of the prior claims. It would not apply to the present claims for the following reasons.

The invention pertains to use of polynucleotides encoding IL-15 polypeptides. Procedures for introducing or use polynucleotide constructs, such as those used in the invention, for gene therapy were well-known in the art as of the date of the invention as disclosed on pages 7-8 of the specification. While the OA cites Danilenko as describing possible gene therapy impediments, others in the art recognized the promise of follicular gene therapy as shown by Ohyama, et al., J. Investig. Dermatol. Symp. Proc. 8(2): 204 (attached, 2003) and Verma, et al., Nature 389: 239 (1997, of record). Thus, it would have been well within the skill of the art to select a suitable type of gene therapy for use within the context of the present invention. Moreover, as discussed in more detail below, the Applicants further support the enablement of the invention with a specific example of the efficacy of targeted gene therapy using polynucleotides expressing IL-15.

The Official Action (page 13, line 4) indicates that the transgenic animal model in Example 2 involves "systemic expression" that would not be used in a gene therapy approach. However, this example does not refer to systemic expression, but rather targeted

keratinocyte-specific expression since the keratinocyte-specific promoter K-14 expression cassette is employed. In accord with Example 2, the new claims require the use of a keratinocyte-specific promoter. Example 2 describes IL-15 expression as being targeted to the epidermis using the K-14 expression cassette. Figure 2a, demonstrates that the expression of IL-15 was restricted to the epidermis of the transgenic mice. The restriction of IL-15 expression to the skin is not achieved by a specific mode of gene therapy but rather by the use of a keratinocyte specific promoter as required by the new claims. Example 2 demonstrates that such a keratinocyte specific promoter can be used to achieve selective expression of IL-15 and thus be useful in targeted gene therapy which avoids systemic expression. Accordingly, this rejection would not apply to the present claims.

Conclusion

This application presents allowable subject matter and the Examiner is respectfully requested to pass it to issue. The Examiner is kindly invited to contact the undersigned should a further discussion of the issues or claims be helpful.

Respectfully submitted,

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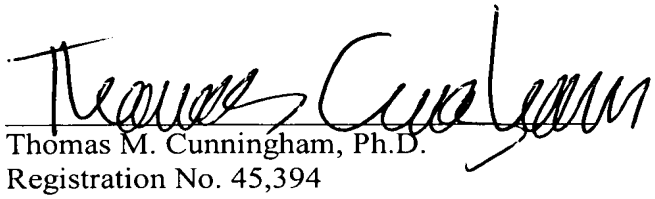
Norman F. Oblon



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